From: "May, David" <DMay@amerisourcebergen.com>
Sent: Thu, 31 Aug 2017 09:52:48 -0400 (EDT)
To: "Miller, Ruth" <rmiller@hda.org>
Subject: RE: HDA Regulatory Reform Meeting with DEA's Diversion Control Division

Thanks for sharing Ruth. David

From: Miller, Ruth [mailto:rmiller@hda.org]
Sent: Wednesday, August 30, 2017 3:49 PM
Subject: HDA Regulatory Reform Meeting with DEA's Diversion Control Division

To: Regulatory Affairs Committee
Legal Committee

At the invitation of the Drug Enforcement Administration (DEA), Patrick Kelly and Ruth Miller of HDA met with DEA Diversion Control Division staff earlier today (Aug. 30) for an "Open Discussion of Regulation and Policy," particularly relating to Executive Order 13777 on Enforcing the Regulatory Agenda. Acting Assistant Administrator Demetra Ashley attended briefly, but the core of the conversation was with Mike Lewis, chief of the regulatory drafting section and two other staff.

This meeting was one of a series that DEA is conducting with trade associations representing different segments of regulated industry. DEA met with pharmacy and practitioner (including veterinary) trade associations yesterday, and is meeting with chemical distributors later today. While organizations representing manufacturers, importers, and exporters had been invited to attend this morning's meeting, none were present.

The conversation, which was cordial and good-natured, focused on the comments that HDA submitted in response to the Department of Justice's solicitation of regulatory reform ideas. Mr. Lewis indicated that HDA's comments are being shared within the agency, and that he is working to understand how the agency might address them, as he has been in his role for only about 14 months. While Mr. Lewis leads the regulatory drafting section, he emphasized that changing DEA's regulations involves many sections within DEA, as well as the Department of Justice and the White House's Office of Management and Budget, and that he is working with all of them on these issues.

Approach moving forward – All three DEA staff members indicated that the Diversion Control Division is committed to improving communications both internally and externally. Mr. Lewis said that he personally is working to "build his Rolodex" so that he can pick up the phone and learn what he needs to know. Likewise, he would like his staff (many of whom are not Diversion Investigators) to be able to visit the field and visit DEA registrants (including distributors) to gain a better understanding of how industry functions before writing regulations. While he was clear that he will continue to be limited in what he can disclose about in-process rulemakings, he appeared to express a genuine commitment to improving communication so as to improve the rules that his unit proposes. He would like to continue to meet, and would like to arrange meetings with individual distributors to understand your concerns firsthand.

"Gray is good"/"Accountability" – We gained a little insight into Mr. Lewis's perspectives about how regulations should be written. While he expressed concern that some of the DEA regulations have remained unchanged since 1971, he also expressed that, based on his experience in the field for DEA, "gray is good," meaning that overly defining requirements can create its own problems. HDA pointed out that while flexibility is necessary, it also is essential that the agency establish parameters so that registrants can understand when they have strayed outside. Mr. Lewis also expressed his view that the agency should clearly convey each registrant's "accountability," so that registrants understand and can accept their responsibilities.

Guidance materials – Mr. Lewis said that the agency has been actively discussing whether they can share more information through sub-regulatory guidance documents. He indicated that they have reviewed FDA's guidance practices as an example. He indicated that, internally, there is openness to considering what the agency might do in this area.

Suspicious Orders Monitoring Rule – Mr. Lewis indicated that his regulatory drafting unit is working on six major regulatory priorities, one of which is a rulemaking on suspicious orders monitoring. He did not offer a timetable but sounded optimistic. He did suggest that the proposed rule "probably would not make everyone happy," and also that he has encouraged his staff to understand that some in industry have sophisticated data analytics, but that others may not have capabilities as advanced. He indicated that his section's highest-priority projects are notices scheduling new illicit (usually fentanyl-related) chemicals on an emergency basis, but that he has increased his staffing.

Sharing of ARCOS data – In response to our request for aggregated, blinded ARCOS data, Mr. Lewis pointed out that DEA is sharing relevant trend data in distributor initiative meetings in select localities. In DEA's view, if they have given a registrant such trend data, that registrant is *on notice*.

Replacing Lou Milione – Lou Milione's replacement as Assistant Administrator (and Chief of the Diversion Control Division) likely will be announced in late September or October.

Please let me know if you have any questions.

Ruth K. Miller, JD
Senior Director, Regulatory Affairs
Healthcare Distribution Alliance (HDA)
rmiller@hda.org
O: 703-885-0266
M: 703-508-0492